

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY

DEPOSITION OF

SHMUEL SHOHAM, M.D.

January 19, 2017



1201 West Peachtree Street
Suite 2300
Atlanta, GA 30309
404.847.0999

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY
SHMUEL SHOHAM, M.D. on 01/19/2017

DEPOSITION OF

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND :
COMPOUNDING PHARMACY, INC. :
PRODUCTS LIABILITY LITIGATION: MDL NO. 2419
:
This Documents Relates to: Master Docket
All Cases against the Box : 1:13-MD-02419-RWZ
Hill Defendants :
:
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DEPOSITION OF
SHMUEL SHOHAM, M.D.

THURSDAY, JANUARY 19, 2017
10:00 a.m.

Law Office of Peter G. Angelos
One Charles Center
100 North Charles Street
Suite 2200
Baltimore, MD 21201

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY
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| 1 A P P E A R A N C E S | | |
| 2 ON BEHALF OF THE PLAINTIFFS: | | 1 P R O C E E D I N G S |
| 3 LAW OFFICES OF PETER G. ANGELOS, P.C. | | 2 Whereupon, |
| 4 Patricia J. Kasputys, Esquire | | 3 SHMUEL SHOHAM, M.D. |
| 5 100 N. Charles Street | | 4 having been first duly sworn, was examined and |
| 6 20th Floor | | 5 testified as follows: |
| 7 Baltimore, MD 21201 | | 6 EXAMINATION BY MR. KIRBY: |
| (410) 649-2000 | | 7 Q Morning, Dr. Shoham. |
| pkasputys@lawpga.com | | 8 A Morning. |
| 8 ON BEHALF OF PLAINTIFF THE ESTATE OF BRENDA ROZEK: | | 9 Q I introduced myself before off the |
| 9 COHEN PLACITELLA & ROTH, P.C. | | 10 record. But for the record, I'm Greg Kirby, and this |
| 10 Michael Coren, Esquire | | 11 is Catherine Steiner, and we represent Dr. Bhambhani, |
| 11 2001 Market Street | | 12 Dr. Bhambhani's LLC, and Box Hill Surgery Center, LLC. |
| 12 Suite 2900 | | 13 Can you spell your name for the record, |
| 13 Philadelphia, PA 19103 | | 14 state and spell your name for the record? |
| (215) 567-3500 | | 15 A The name is Shmuel Shoham. And it's |
| mcoren@cprlaw.com | | 16 spelled S-H-M-U-E-L, last name S-H-O-H-A-M. |
| 14 ON BEHALF OF BOX HILL SURGERY CENTER, RITU BHAMBHANI, | | 17 Q And if I mispronounce it at all, just |
| 15 M.D., RITU BHAMBHANI, M.D., LLC: | | 18 correct me, okay? I will do my best. |
| 16 PESSIN KATZ LAW, P.A. | | 19 What's your address, your business address? |
| 17 Gregory K. Kirby, Esquire | | 20 A 1830 East Monument Street, Baltimore, |
| 18 Catherine Steiner, Esquire | | 21 Maryland. |
| 19 901 Dulaney Valley Road | | 22 Q Okay. You're under oath. You know that, |
| 20 Suite 500 | | 23 right? This is my only opportunity to find what your |
| 21 Towson, MD 21204 | | 24 opinions are, so I'm hopeful to get complete answers. |
| (410) 769-6143 | | 25 To that end, if I ask a question that you don't |
| 22 gkirby@pklaw.com | | |
| 23 | | |
| 24 | | |
| 25 | | |
| 1 I N D E X | Page 3 | Page 5 |
| 2 Videotaped Deposition of: | Page | 1 understand, can you just ask me to repeat it or |
| 3 SHMUEL SHOHAM, M.D. | 4 | 2 rephrase it? |
| 4 Examination by Mr. Kirby | Page | 3 A Yes. |
| 5 | 4 | 4 Q And if you answer a question, I'll assume |
| 6 | | 5 that you understood the question, that you answered it |
| 7 E X H I B I T S | | 6 as completely as you could. Is that fair? |
| 8 (Attached to the transcript) | | 7 A Yes. |
| 9 No. | Page | 8 Q Okay. The court reporter is typing down |
| 10 Exhibit 1612-1 Notice of Deposition | 5 | 9 everything that we say, and so she can't record nods |
| 11 Exhibit 1612-2 Report of Dr. Shoham | 7 | 10 of the head or uh-hums, uh-uhs, that kind of stuff. |
| 12 Exhibit 1612-3 Curriculum vitae, 8/25/16 | 8 | 11 So we just need to make sure we say yes or no. |
| 13 Exhibit 1612-4 Trial and Deposition List, | 26 | 12 It's normal in conversation that we might |
| 14 2011-Present | | 13 end up talking over each other. I'll do my best not |
| 15 Exhibit 1612-5 Letter dated 10/20/16 re | 29 | 14 to do that, if you can do that as well. |
| 16 invoice | | 15 A Yes. |
| 17 Exhibit 1612-6 Maryland Board of Pharmacy News | 45 | 16 Q And if you need a break at any point, just |
| 18 Newsletter, Fall 2012 | | 17 let me know and we can take a break. Okay? |
| 19 C I T E D | | 18 A Yes. |
| 20 Exhibit 1585-12 New England Compounding Center | | 19 Q The plaintiffs' counsel identified you as |
| Customer List since May 21, 2012, | | 20 an expert on behalf of the plaintiffs. Is that your |
| Sorted by State | | 21 understanding as to why you are here? |
| 21 Exhibit 1089 Article, "Spinal and Paraspinal | | 22 A Yes. |
| Fungal Infections Associated | | 23 (Exhibit No. 1612-1 was marked for |
| with Contaminated | | 24 identification.) |
| Methylprednisolone Injections" | | 25 Q I want to mark -- I'll show you what's been |
| 23 | | |
| 24 Exhibit 1619-10 Article, "Price of Cost Savings" | | |
| 25 | | |

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| <p style="text-align: right;">Page 42</p> <p>1 going to give opinions about -- you were going to give 2 opinions concerning being a medical doctor, in 3 general, not a pain specialist?</p> <p>4 MS. KASPUTYS: Objection.</p> <p>5 A That's what we talked about. But they 6 weren't telling me what to do. They were saying that 7 that is something that I can do.</p> <p>8 Q They said it's something you can do?</p> <p>9 A As I recall. I don't recall the specific 10 words.</p> <p>11 Q And did that have to do with standard of 12 care or what did it have to do with?</p> <p>13 A Standard of care.</p> <p>14 Q So why don't you give me your opinions with 15 regards to that, as a medical doctor, and how it 16 relates to a standard of care in this case.</p> <p>17 A So my opinions regarding standard of care 18 in this case are in the report.</p> <p>19 Q Okay. But can you point me to where it is?</p> <p>20 A Page 3 is a specific example.</p> <p>21 Q What part of page 3?</p> <p>22 A Third paragraph.</p> <p>23 Q Okay. So let's look at the first 24 paragraph, the first full paragraph on page 3. It 25 says, "The manner by which the contaminated steroids</p> | <p style="text-align: right;">Page 44</p> <p>1 applicable to prescribing prescription medicines," and 2 then describes, I guess, some other opinions in here. 3 But what Maryland law are you referring to?</p> <p>4 A I can give you -- the specific newsletter 5 is number 13 on page 5, Board of Pharmacy Newsletter, 6 Fall 2012.</p> <p>7 Q Okay. Do you have a copy of that?</p> <p>8 MS. KASPUTYS: That's in the documents that 9 were produced for you. Third tab.</p> <p>10 MR. COREN: Third tab?</p> <p>11 MR. KIRBY: I'm not saying you didn't send 12 it out. I'm just saying I don't see a copy of it.</p> <p>13 MS. KASPUTYS: Greg, I'll give you one to 14 look at.</p> <p>15 MR. KIRBY: Okay.</p> <p>16 MS. KASPUTYS: If I can get it out of the 17 binder. There you go.</p> <p>18 MR. KIRBY: Thanks.</p> <p>19 MS. KASPUTYS: Oh, wait a minute. Let me 20 give you the rest of the pages. There you go.</p> <p>21 MR. KIRBY: I'd like to mark this as an 22 exhibit. Can we make a copy?</p> <p>23 MS. KASPUTYS: Go ahead. You can use that. 24 Just take it. I have a stapler if you need one.</p> <p>25 BY MR. KIRBY:</p> |
| <p style="text-align: right;">Page 43</p> <p>1 reached patients did not always conform to the 2 standards of care. A specific example is the method 3 and manner in which PF MPA from NECC was prescribed, 4 ordered, and administered at Box Hill Surgery Center 5 in Maryland."</p> <p>6 So what do you mean by that? Like, be more 7 specific.</p> <p>8 A So the way that the products were 9 prescribed, according to the testimony that I've read, 10 were that patients who had previously been seen at the 11 surgical center, their names were provided as a list 12 and vials were ordered using those names.</p> <p>13 And then those vials would come and those 14 vials were sometimes given to patients who were 15 different than the ones that it was prescribed for. 16 And additionally, the single use vials were at times 17 used more than one time for one patient for one 18 procedure.</p> <p>19 Q Okay. You've never purchased drugs for an 20 ambulatory surgery center before, right?</p> <p>21 A Not that I recall.</p> <p>22 Q Okay. And you don't generate, manage, and 23 treat chronic pain patients, correct?</p> <p>24 A That is correct.</p> <p>25 Q Now, it says in here "under Maryland law</p> | <p style="text-align: right;">Page 45</p> <p>1 Q Doctor, have you found the newsletter you 2 were referring to in your binders?</p> <p>3 A Yes. It's on page 7 of the newsletter 4 that's called "Maryland Board of Pharmacy News," Fall 5 2012.</p> <p>6 Q I'm sorry, can you say that one more time?</p> <p>7 A Maryland Board of Pharmacy News, Fall 2012, 8 page 7.</p> <p>9 Q Okay. So we're going to mark this, it's 10 the same thing you have, as 1612-6, for the record. 11 (Exhibit No. 1612-6 was marked for 12 identification.)</p> <p>13 Q As a physician, you don't regularly receive 14 newsletters from the Board of Pharmacy, do you?</p> <p>15 A I may. I'm not sure.</p> <p>16 Q Okay. You don't seek out and review 17 newsletters from the Board of Pharmacy, do you?</p> <p>18 A In preparation for this case, I reviewed 19 this material.</p> <p>20 Q So I mean, in the normal course of your 21 practice.</p> <p>22 A I may receive it.</p> <p>23 Q You're talking about you receive Maryland 24 Board of Pharmacy newsletters?</p> <p>25 A I may. I'm not sure.</p> |

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| <p style="text-align: right;">Page 106</p> <p>1 for multiple patients or for multiple procedures in 2 the same patient is not standard of care.</p> <p>3 Q Okay. And are you familiar with any 4 literature that suggests that, I guess, "single-dose 5 dose vials can be used on multiple patients under 6 certain circumstances with certain precautions that 7 are taken"?</p> <p>8 A I have seen a reference that is an opinion 9 by some people.</p> <p>10 Q Okay. So you wouldn't disagree that some 11 in medicine accept the practice of using single-dose 12 vials multiple times as long as they follow certain 13 precautions?</p> <p>14 A That is an opinion. That is not what the 15 CDC recommends. The CDC recommends against it.</p> <p>16 Q All right. If other reasonably prudent 17 practitioners believe that it's okay to do it as long 18 as there are certain precautions taken, isn't that the 19 definition of standard practice?</p> <p>20 MR. COREN: Objection as to form.</p> <p>21 MS. KASPUTYS: Object to form.</p> <p>22 Q Maybe not everyone agrees. You have one. 23 Someone else has a different opinion. But that 24 doesn't mean that just because it's different than 25 your opinion that it's wrong, correct?</p> | <p style="text-align: right;">Page 108</p> <p>1 A Yes.</p> <p>2 Q "And the push for cost-efficient care, a 3 case can made for safely reusing a single-dose 4 medication." See that?</p> <p>5 A I see that.</p> <p>6 Q And then under there, it's a description of 7 -- I'm just going to read it. You can follow along.</p> <p>8 It says, "If a practitioner chooses to reuse a 9 single-dose medication, there must be strict 10 safeguards in place that minimize the risk of 11 infection. These include using the medication for a 12 limited number of patients and for a single day only, 13 cleansing the stopper thoroughly between uses with 14 isopropyl alcohol or another suitable antimicrobial. 15 Refrigeration of vial between cases if there is a time 16 gap between consecutive cases and discarding the vial 17 if any breach or sterility is suspected."</p> <p>18 And then it goes on to say, of course, you 19 only, you know, use a needle, one needle per patient, 20 et cetera.</p> <p>21 If that is the process by which Dr. 22 Bhamhani administers the drug and "reuses the 23 single-dose vial," she follows those precautions, 24 would you agree that according to this article, she's 25 complying with an accepted standard of practice?</p> |
| <p style="text-align: right;">Page 107</p> <p>1 A You said a lot of things there.</p> <p>2 Q I did, didn't I? There's not always one 3 way to satisfy the standard of care, right? There's 4 sometimes more than one standard practice, right?</p> <p>5 A As a general statement?</p> <p>6 Q As general statement, right.</p> <p>7 A There are different ways to do things.</p> <p>8 Q And I want to just hand you what's been 9 previously marked as 1619-10. It's an article. At 10 the top, just for the record, that says it's titled 11 "The Price of Cost Savings," Ray M. Baker, in the 12 Clinical Journal of Pain, June of 2008.</p> <p>13 And did you review in Dr. Bhamhani's 14 deposition her description of the process and how she 15 administers the injection and what precautions she 16 takes?</p> <p>17 A Yes.</p> <p>18 Q Okay. So if you look at the second page of 19 this article, page 382, if you look at the right 20 column, the second paragraph up from the bottom, it 21 starts off "If a practitioner chooses."</p> <p>22 A Yes.</p> <p>23 Q And actually if you look a few lines up 24 from that, it says, "Given the reduced reimbursements 25 for interventional pain procedures." Do you see?</p> | <p style="text-align: right;">Page 109</p> <p>1 MR. STEINER: Objection as to form. You 2 can answer.</p> <p>3 A According to the CDC, in which I place more 4 credence than this opinion, a single vial, a 5 single-dose vial should not be reused. And I don't 6 know why this clinician opined as he did. But even in 7 2012, I would not say that this was a reasonable 8 opinion based on the history of multiple outbreaks 9 related with reusing of single-dose vials.</p> <p>10 Q Do you know Dr. Baker?</p> <p>11 A No.</p> <p>12 Q Are you familiar with this journal?</p> <p>13 A I've heard of it.</p> <p>14 Q Do you have an opinion, one way or the 15 other, whether this journal is a reasonably reliable 16 journal?</p> <p>17 MR. COREN: Objection as to form.</p> <p>18 A I don't.</p> <p>19 Q And so you would disregard the expressions 20 made here this literature?</p> <p>21 A I do not think that the statement of given 22 the reduced reimbursements for interventional pain 23 procedures and the push for cost-efficient care, a 24 case can be made for safely reusing a single-dose 25 medication, and that this is something that could be</p> |